

Appl. No. 09/940,273
Amdt. Dated July 13, 2005
Reply to Office Action of January 13, 2005

REMARKS

The following remarks are submitted in response to the Office Action mailed January 13, 2005. Claims 1-52 and 137-219 are withdrawn from consideration. Therefore, claims 53-136 are pending and remain under consideration. Reconsideration, reexamination and allowance of the pending claims are respectfully requested.

ALLOWABLE SUBJECT MATTER

Applicants thank the Examiner for indicating that claim 76 is allowed and claims 117 and 118 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

35 U.S.C. § 102 CLAIM REJECTIONS

Claims 53, 54, 63, 70-72, 74, 75, 77, 84-90, 95, 96, 105, 112-114, 116, 119 and 126-136 are rejected under 35 U.S.C. §102(b) as being anticipated by Hauser et al. (U.S. 5,385,574). The Examiner asserts that Hauser et al. disclose an implantable cardioverter-defibrillator comprising a housing, an electrical circuit located within the housing, first and second electrodes coupled to the electrical circuit, wherein the first and second electrodes are positioned on substantially opposite sides of the patient's heart. The Examiner states that "subcutaneous" has been interpreted to mean under the skin. Applicants respectfully traverse the rejection.

A similar rejection over Hauser et al. was made in the Office Action mailed February 11, 2004. In response Applicants amended independent claims 53 and 95 to specify the two electrodes are subcutaneous and that the cardioversion-defibrillation energy is delivered between the first and second subcutaneous electrodes. As stated in Applicants' response filed May 11, 2004, while Hauser et al. do indicate that a subcutaneous electrode may be used in the system, for example, at column 6, lines 8-17, Hauser et al. do not teach or suggest delivering a cardioversion-defibrillation energy between two subcutaneous electrodes. In Hauser et al., transvenous electrodes, such as an electrode positioned in the right-atrium (RA), the superior vena cava (SVC), or the right ventricle (RV) are used in conjunction with the active can or the subcutaneous electrode to deliver energy. See, Hauser et al. at column 4, line 56 through column 5, line 2; and column 5, line 67 through column 6, line 17. There is no teaching or suggestion of

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delivering energy between the active can and the subcutaneous electrode. As such, there is no teaching or suggestion of first and second subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

The Examiner points to the same reference numerals in the Hauser et al. figures as anticipating both the first and second subcutaneous electrodes. The claims recite a cardioversion-defibrillation energy is delivered between the first and second subcutaneous electrodes. In order to properly respond to the rejection, Applicants request the Examiner to specify which electrodes in the Houser et al. device are being interpreted as the first electrode and which are being interpreted as the second electrode.

The Examiner appears to be interpreting "subcutaneous" as meaning anywhere and at any level under the skin, including inside the heart or inside a vessel. Applicants submit that such an interpretation is contrary to the meaning of "subcutaneous" as is understood by those of ordinary skill in the art. MPEP 2111, quoting *In re Morris*, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), states that

the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.").

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)

(emphasis added). MPEP 2111 (II), citing *Sunrace Roots Enter. Co. v. SRAM Corp.*, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003), states that claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art.

One of ordinary skill in the art would not identify an electrode, lead, or lead system residing at least in part within a patient's vasculature or at least in part within a patient's heart as a "subcutaneous" electrode, lead, or lead system. Rather, in the context of cardioversion defibrillation treatment of a patient, an electrode, lead, or lead system that resides at least in part within a patient's vasculature or at least in part within a patient's heart is identified as a transvenous electrode, lead, or lead system. Applicants submit that those of ordinary skill in the art of implantable cardioverter-defibrillators would not interpret the transvenous electrodes of

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Hauser et al. to be "subcutaneous." Hauser et al. teach at best one subcutaneous electrode used in combination with a transvenous electrode. Therefore, Hauser et al. do not teach the invention of claim 53.

With respect to claims 54, 72, 96 and 114, the Examiner asserts that Hauser et al. disclose at least a portion of the housing or electrode is curved. FIG. 7 of Hauser et al. merely shows that the edges of the housing are curved. The claims recite "at least a portion of the housing is curved to focus cardioversion-defibrillation energy emitted from the first electrode in the predetermined direction" (emphasis added). Applicants submit that Hauser et al. do not teach or suggest the curved housing edges of Hauser et al. to focus cardioversion-defibrillation energy emitted from an electrode.

Claims 70, 71, 112 and 113 recite the first electrode can further receive sensory information. The Examiner asserts that Hauser et al. disclose the first electrode can further receive sensory information. Hauser et al. actually disclose, at column 7, lines 9-15, that "[o]ne or two of these regions may be dedicated for sensing purposes while others may be dedicated for shocking purposes." Hauser et al. thus teach separate regions for sensing and shocking. Hauser et al. thus do not teach the elements of the claims.

Claim 77 recites the second electrode is disposed on a lead. Claim 77 depends from claim 53, which recites the second electrode is a subcutaneous electrode. The second electrode in claim 77 is thus a subcutaneous electrode. The Examiner points to electrodes 28 or 29 as the "second electrode" disposed on a lead as taught by Hauser et al. Hauser et al. teach that in operation the lead is implanted "in the human heart 38 with electrode 28 in the right ventricle 40 and electrode 29 proximate the right atrium or the superior vena cava 42." See column 5, lines 51-54. As discussed above, one of ordinary skill in the art would not interpret Hauser et al.'s electrodes implanted in the heart as being "subcutaneous" as is recited in claim 77.

With respect to independent claim 95, the Examiner asserts that electrodes 28 and/or 29 of Hauser et al. are "subcutaneous." As stated above, Hauser et al. clearly teach the electrodes 28 and 29 implanted in the heart. Applicants submit that the ordinary and customary meaning of "subcutaneous" attributed to the term by those of ordinary skill in the art would not include the Hauser et al. electrodes implanted in the heart. Additionally, claim 95 recites the first and second subcutaneous electrodes spaced apart with a degree of separation in the range of

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approximately 30 degrees to approximately 180 degrees. The Examiner has not indicated which electrodes of Hauser et al. are considered the first and second subcutaneous electrodes of claim 95 such that the electrodes have the claimed configuration. Hauser et al. thus do teach the elements of independent claim 95. For similar reasons, Hauser et al. do not teach the elements of dependent claim 119.

For the reasons set forth above, it is believed that independent claims 53 and 95, and the claims depending therefrom, are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103(a) CLAIM REJECTIONS

Claims 55-58, 73, 78-83, 91-94, 97-100, 115, 120-125 and 132-136 are rejected as being unpatentable over Hauser et al. The rejected claims are all dependent on independent claims 53 and 95, which are patentable over Hauser et al. for at least the reasons set forth above. Additionally, Hauser et al. teach one subcutaneous electrode and one electrode implanted in the heart or in a vessel; thus there is no motivation or guidance for one of ordinary skill in the art to modify the device of Hauser et al. to have first and second subcutaneous electrodes. Withdrawal of the rejection is respectfully requested.

Claims 59-62 and 101-104 are rejected as being unpatentable over Hauser et al. in view of Mouchawar (U.S. 5,601,608). Claims 64-69 and 106-111 are rejected as being unpatentable over Hauser et al. in view of Ostroff (U.S. 5,215,081). Claims 59-62, 64-69, 101-104 and 106-113 are all dependent on claims 53 or 95, which are patentable over Hauser et al. for at least the reasons set forth above. Neither Mouchawar nor Ostroff provides what Hauser et al. lack. Additionally, there is no motivation for one of ordinary skill in the art to modify the device of Hauser et al. to achieve the claimed invention. Withdrawal of the rejections is respectfully requested.

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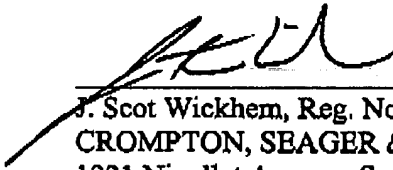
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

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